Certificate No: **GMP 239/4**

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with the requirements of Good Manufacturing Practice, of the Israeli laws and regulations (Pharmacist Regulations [Good Manufacturing Practice for Medicinal Products] 2008)

and

Issued under the provisions of the Conformity Assessment and Acceptance of Industrial Products (CAA) Agreement between the European Union and Israel

The competent authority of Israel confirms the following:

The manufacturer	**S.R.Y. (Medical Services) Ltd.**
Site address	**1 Kalman Man St., P.O.B. 12000, Jerusalem, 9112001, Israel**

Has been inspected under the Israeli inspection programme, in connection with manufacturing authorization no. **MIA 239**, in accordance with the above mentioned laws and regulations

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **19-22 January 2025**, it is considered that it complies with the Good Manufacturing Practice requirements referred to in the Conformity Assessment and Acceptance of Industrial Products (CAA) Agreement between the European Union and Israel and the above mentioned Israeli laws & regulations(*).

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than **three years** have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field.

This certificate is valid only when presented with all pages and both Parts 1 and 2.

The authenticity of this certificate may be verified in EudraGMP.
If it does not appear, please contact the issuing authority.

(*) these requirements fulfill the GMP recommendations of WHO

MINISTRY OF HEALTH JERUSALEM
GOV. INSTITUTE FOR CONTROL AND STANDARD OF PHARMACEUTICALS
משרד הבריאות

10.3.25

מיכאל כוגן
ע. מפקח ארצי
תנאי יצור נאותים

Ministry Of Health, MTIR Directorate
The Institute for Standardization and Control of Pharmaceuticals
9 Eli'av St., Jerusalem, 9546208, Israel
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Part 2

HUMAN MEDICINAL PRODUCTS

1. MANUFACTURING OPERATIONS –MEDICINAL PRODUCTS

1.1 Sterile products

1.1.1 Aseptically prepared

1.1.1.4 Small volume liquids

1.1.3 Batch certification

1.5 Packaging

1.5.1 Primary packing

1.5.1.6 Liquids for internal use

1.5.2 Secondary packing

1.6 Quality control testing

1.6.1 Microbiological: sterility

1.6.3 Chemical/Physical *(including LAL)*

Any restrictions or clarifying remarks related to the scope of this certificate:

This certificate is relevant to ^{177}Lu-DOTA-TATE (LuNET- SRY), a radiopharmaceutical for cancer therapy.

Name and signature of the authorized person of the Competent Authority of Israel:

Michael Carmi, Pharmacist - GMP Inspector

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phone: office 972 -2-6551795, cell 972-50-6242452

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